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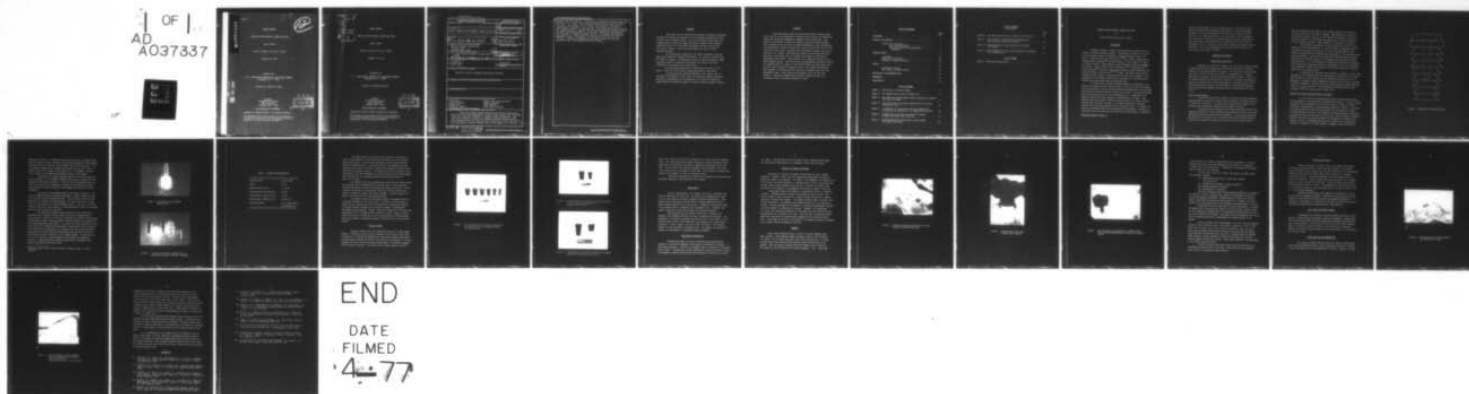
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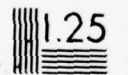
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REPORT NUMBER 7

SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

Annual Report

Craig R. Hassler and Larry G. McCoy

November 30, 1976

Supported by

U. S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
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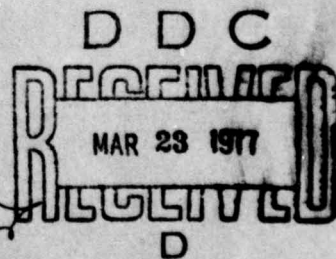
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Columbus Laboratories
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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) <p>Long term implant studies involving high density alumina Al_2O_3 tooth roots have been undertaken in baboons using a single root elipitfical design with serrations designed for maximal stress distribution. The roots are produced by cutting on a computer controlled milling machine. This technique allows for sizes and shape flexibility, stress distribution area maximization, greater strength and a better quality root than was</p>		

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possible with slip casting. Implants have successfully remained rigid and in function up to 2 years. Both fresh and edentulous extraction sites have been used. The success rate for ingrown roots placed in function is approximately 90 percent. Most failures occur during the initial 2 to 3 month ingrowth period. The success rate is approximately 60 percent during the ingrowth period in baboons. This initial period has been found to be the most crucial period for implant success. Once firmly stabilized by bone ingrowth, a prefabricated post and core is cemented into place and impressions taken. Gold crowns are fabricated to put the root into function. Histologic examinations show dense ingrowth of bone into serrations with no intervening connective tissue.

FOREWORD

This study has been conducted at Battelle's Columbus Laboratories utilizing the talents and resources of the Bioengineering/Health Sciences Section and the Ceramics Section. This is the Seventh Annual Report on progress under Contract No. DADA17-69-C-9181, "Surgical Tooth Implants, Combat and Field". The Principal Investigator for this research was Dr. Craig R. Hassler. He was ably assisted by Mr. Larry G. McCoy, Principal Ceramist.

We are gratefully indebted to our dental consultants from The Ohio State University, College of Dentistry: Dr. Orville E. Russell and Dr. Robert H. Downes. The individual talents of these gentlemen in their respective fields of expertise has allowed this project to proceed successfully during the current project year.

We would additionally like to acknowledge the efforts of Mr. Lynn C. Clark for the histologic preparations used in this report.

In conducting the research described in this report, the investigators have adhered to the "Guide for Laboratory Animals Facilities and Care: as promulgated by the Committee on the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

ABSTRACT

Long term implant studies involving high density alumina Al_2O_3 tooth roots have been undertaken in baboons using a single root elipitcal design with serrations designed for maximal stress distribution. The roots are produced by cutting on a computer controlled milling machine. This technique allows for sizes and shape flexibility, stress distribution area maximization, greater strength and a better quality root than was possible with slip casting. Implants have successfully remained rigid and in function up to 2 years. Both fresh and edentulous extraction sites have been used. The success rate for ingrown roots placed in function is approximately 90 percent. Most failures occur during the initial 2 to 3 month ingrowth period. The success rate is approximately 60 percent during the ingrowth period in baboons. This initial period has been found to be the most crucial period for implant success. Once firmly stabilized by bone ingrowth, a prefabricated post and core is cemented into place and impressions taken. Gold crowns are fabricated to put the root into function. Histologic examinations show dense ingrowth of bone into serrations with no intervening connective tissue.

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SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

by

Craig R. Hassler and Larry G. McCoy

BACKGROUND

Research interest in dental restorations has continued to be a subject of intense research interest. Of particular interest in this project are implants which are designed to replace individual teeth. As noted in previous reports on this project,^{(1-7)*} a group of materials including porous titaniums,⁽⁸⁾ vitreous carbons,⁽⁹⁾ and ceramics⁽⁷⁾ remain of serious interest. Additionally, several different design philosophies are evident. They include: solid rod and shafts,⁽⁸⁾ screw devices,⁽¹²⁾ porous titanium⁽¹¹⁾ devices of both uniform and non-uniform porosities and serrated designs of three basic^(7,9,11) types. The device which will be discussed in this report is serrated with the serrations arranged in such a manner that the maximal surface area is available for distribution and minimizing stresses placed upon the adjacent bone.

In recent years, materials mentioned above have remained in contention for prosthetic tooth roots as well as for use in other body replacement areas because of their previously observed biocompatibility even though more successful materials may be evolved in the future. The above-mentioned materials persist because of their biocompatibility. Consequently, the greater problem with today's implants is biomechanical in nature. Most difficulties arise because a complex structure such as the tooth is being replaced with a foreign structure. Attachment between the artificial material and the natural alveolar bone is of great concern. At present two different attachment modalities are mentioned by researchers. Design configurations such as porous pins and studs are serrated devices to provide an

*References begin on page 20.

implant which attempts to form a rigid fixation. On the other hand, some researchers have indicated the necessity for a pseudoperiodontal ligament to be regenerated between the tooth root structure and bone. The tooth root design described in this report most closely resembles a rigid fixation. This design and similar designs by other researchers is successful because mastication forces applied upon the tooth root are distributed in such a manner that the stress placed upon alveolar bone is minimized. This is the fundamental concept upon which the tooth root described in this report is based.

MATERIALS AND METHODS

Alumina Root Structures

High-density, high-purity alumina root structures having a tapered serrated surface and incorporating a recessed top and hollow core were prepared for in vivo evaluation in baboons. The objective of these evaluations was to verify further the efficacy of the design and to provide additional histological data on long-term functional implants. Prior to the implant fabrication, studies were conducted to optimize the design for improved restoration and occlusal load support. To fully utilize the resulting design modifications, new fabrication techniques were developed which significantly improved the definition and reproducibility of tooth detail.

Root Structure Design

During the 1974 and 1975 programs a new root structure design was developed which incorporated a hollow core and concentric elliptical recess to facilitate restoration. In vivo studies conducted with implants incorporating this termination concept have been highly successful.

During the present program, several improvements were made in the termination details to further facilitate restoration as well as to provide improved fabricability and structural integrity. The previous square core was modified to a conical core to facilitate casting of the gold post and core and to eliminate the corner stress-risers in the finished ceramic.

This also simplified fabrication of the ceramic since the core can now be drilled after the root shape is formed. Additionally, the contour of the exterior surface at the top of the implant was modified to provide a distinct finish line to facilitate the preparation of a better margin at the gold/ceramic interface. These changes are illustrated in Figure 1.

The dimensions and details of the serrated root section of the implant have also been modified. To provide a closer dimensional match to the natural dentition of the baboon, the cross sectional shape of the implant has been made more elliptical and the length of the serrated section has been increased. The excentricity (difference between major and minor axes) has been increased from 1 to 2 millimeters and the serrated length increased from 7.5 to 12 millimeters by adding three additional serrations. These dimensional changes were based on measurements of the root dimensions of approximately twenty teeth extracted from various maxillary and mandibular, molar and premolar sites

To maximize the horizontal area available to support occlusal loads, the depth of the serrations was also increased by 50 percent (1 to 1.5 mm). Basic research on other projects in this laboratory indicates that it is desirable to maintain stress concentrations below 350 psi in bone to prevent resorption phenomena. The root structures modifications described above provide in all cases except the 7 and 8 mm sizes stresses below this level assuming a 160 pound static-axial occlusal load.

Materials Selection and Fabrication Procedures

To fully utilize the design detail modifications discussed above, the development of new fabrication techniques was necessary. The slip casting techniques used previously do not have the ability to provide the detail definition, reproducibility, and processing flexibility required. A process of contour grinding the root structure shape from dry-pressed or bisque-fired material was selected. This technique is used extensively in industry to fabricate precision electrical and electronic ceramic insulator components. However, since the cross-sectional shape of the implant is elliptical instead of circular, a machining procedure more complex than a simple lathe operation is required. For this purpose, a computer controlled milling

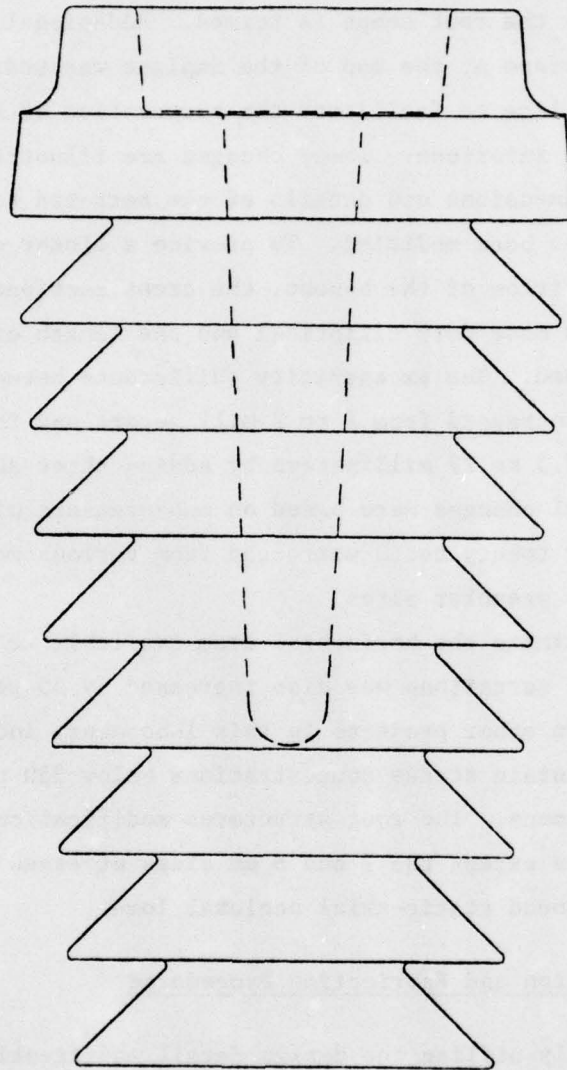


FIGURE 1. IMPROVED ROOT STRUCTURE DESIGN

machine was utilized. To generate the elliptical shape, an indexed rotary table was used to support the blank rod stock and the depth of the grinding head was varied as a function of the angular rotation of the piece. (i.e., the computer program for an ellipse was written in terms of $R = f(\theta)$). A change in the size or shape of the ellipse (i.e., the implant) requires only a change in the maximum and minimum R values of the program.

To generate the complete external contour of the root structure shown in Figure 1; a full length, diamond-plated contour grinding tool was designed and fabricated (Figure 2). The tool has the negative contour of the root structure and is designed to produce an as-ground shape that is approximately 13 percent oversize in all dimensions to allow for firing shrinkage.

The steps in the grinding operation are shown in Figure 3. The blank is preground using conventional equipment to remove excess material and to provide a smooth gripping surface. The elliptical contour is then ground on the computer-controlled machine. The root structure is ground in the inverted position to provide maximum support. The root is cut away from the stump and is then mounted in a matching plastic holder for grinding the recess and drilling the post hole.

The experimental implants were fabricated from a high-purity, extremely fine, thermally reactive grade (A-16 SG)* of alumina powder. This material is noted for its ability to produce very uniform, fine-grained, high-strength ceramics having densities above 98 percent of theoretical at sintering temperatures below 3000 F. Its purity is nearly identical to that of the Alcoa A-17 alumina used previously to slip-cast the root structures. Prior experience has shown that, as a result of the use of dry processing procedures and reduced sintering temperatures, more uniform defect-free microstructures can be achieved in the finished ceramic. The characteristics of the material at various stages in the process are summarized in Table 1. Microstructural characterizations will be completed after implant requirements have been filled.

*Alcoa A-16 Super Ground, Alumina Company of America, East St. Louis, Illinois.

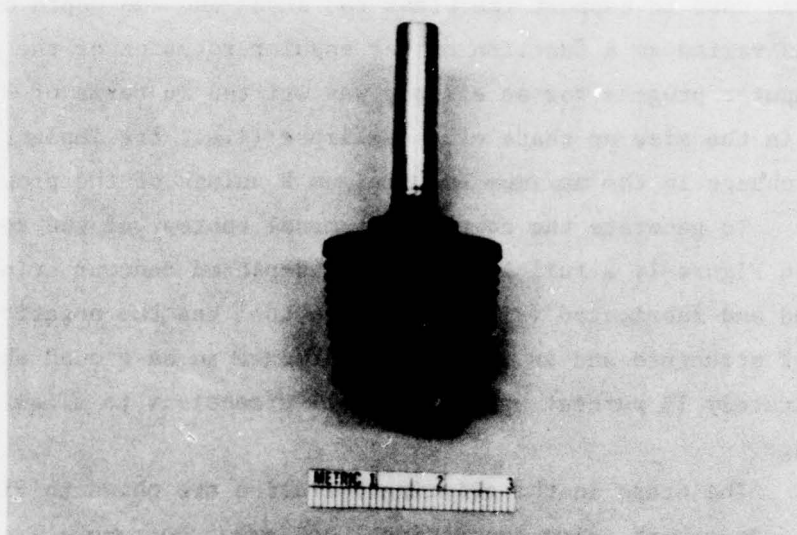


FIGURE 2. THE DIAMOND PLATED CONTOUR GRINDING TOOL

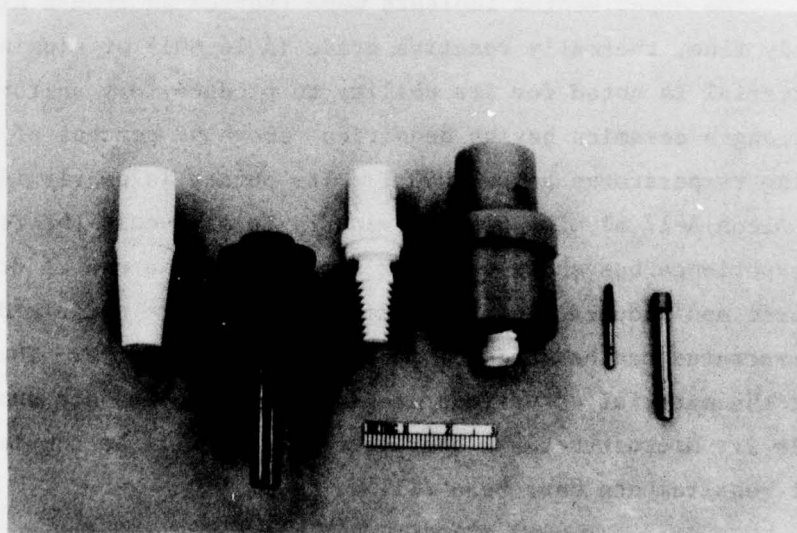


FIGURE 3. THE STEPS AND TOOLING SEQUENCE USED TO MACHINE THE ALUMINA TOOTH ROOT STRUCTURES

TABLE 1. MATERIAL CHARACTERISTICS

Alumina Powder	Alcoa A-16SG
Purity	99.8+
Median Particle Size	<1 micron
Pressed density (50,000 psi)	57-58%
Bisque density (2100 F/2 hrs)	61-63%
Fired density (3000 F/2 hrs)	98.5-99.3%
Firing Shrinkage	14.2% longitudinal 12.8% diametral

The alumina powder was isostatically pressed at 50,000 psi to form 1/2-inch diameter x 2-inch long rods from which the root structure shapes were ground. Initial contour grinding trials were conducted by using as-pressed material. Excessive filling of the grinding tool and chipping at the edges of the piece dictated that grinding of bisque (soft) fired pieces would be necessary. Preliminary dry and wet grinding trials indicated that the best compromise in terms of surface finish and grinding rate occurred with wet grinding of material that had been fired at 2100 F for 2 hours.

The primary difficulty encountered in utilizing the contour grinding technique was the seemingly high tool wear rate. It was necessary to strip and replat the tool once during the production cutting. Several iterative variations of cutting depth, feed rate, and tool speed were required to finish the implant fabrication schedule. Further studies are needed to optimize tool life and grinding speeds.

Six implant sizes were fabricated, Figure 4, ranging from 12 to 7 mm (major diameter at the finish line). All have a 2 mm excentricity except the No. 7 implant which was fabricated with a 6-mm minor diameter to provide adequate strength for the contour grinding. Approximately 100 implants were prepared. Figure 5 presents a comparison of the size and appearance of a No. 10 implant before and after firing. Figure 6 illustrates definition of design detail that can be achieved by the machining process as compared to implants previously fabricated by the slip-casting process.

IMPLANT STUDIES

Implant procedures have been performed primarily in adult female baboons. Following a extraction, the mandibular tooth socket, either molar or premolar, is enlarged and deepened with specially designed tapered diamond burr made to match the taper of the serrated tooth implants. A fitting procedure is used in which the socket being formed is continually examined for fit using a size gage. The roots are then firmly tapped into place.

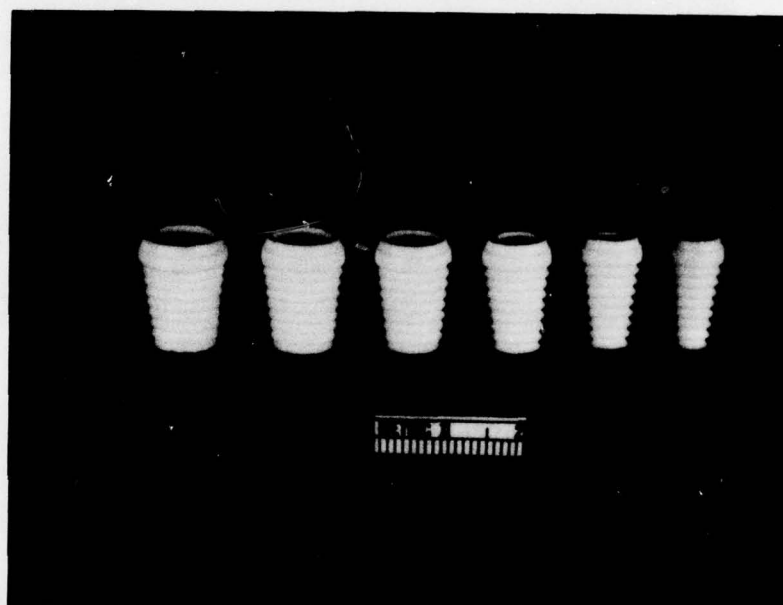


FIGURE 4. THE FINISHED ROOT STRUCTURES FABRICATED BY THE CONTOUR GRINDING PROCEDURE (SIZES 7 THROUGH 12 mm)

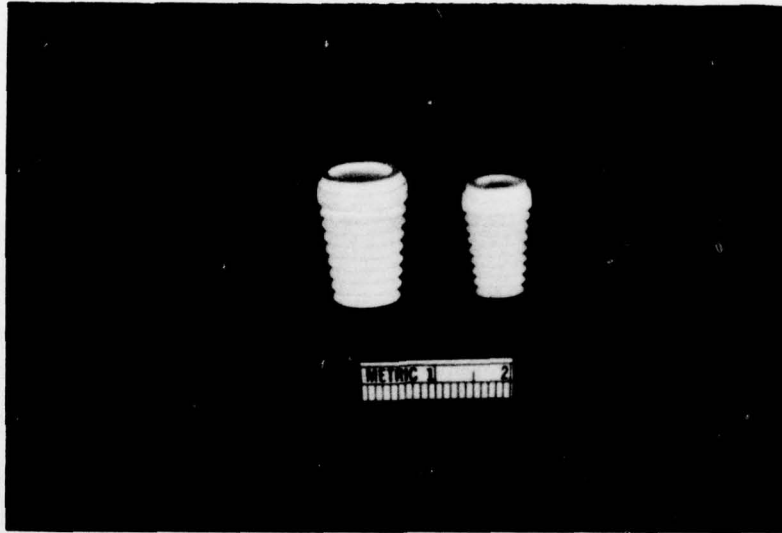


FIGURE 5. A COMPARISON OF THE RELATIVE SIZE AND APPEARANCE OF AN AS-GROUND AND SINTERED NO. 10 ALUMINA ROOT STRUCTURE

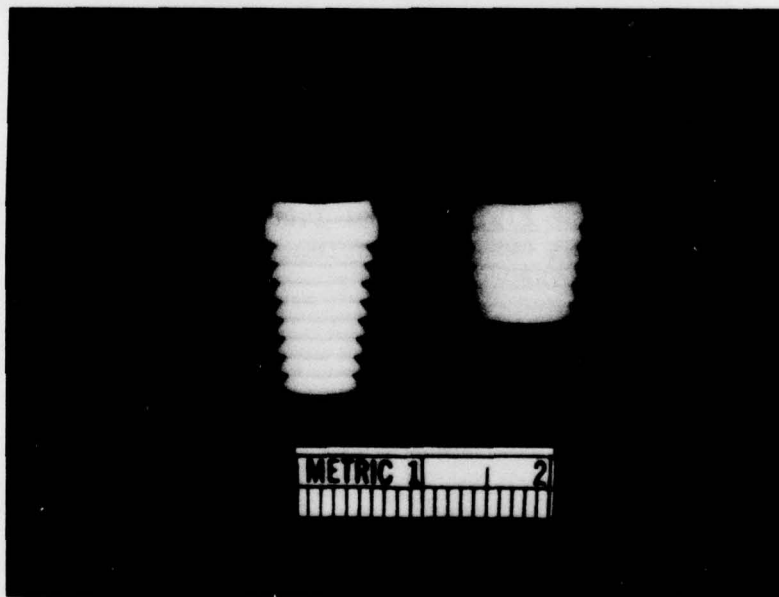


FIGURE 6. A COMPARISON OF THE DETAIL PRECISION OF CONTOUR-GROUND VS SLIP-CAST ROOT STRUCTURES

The root is sunk until the first serration is in contact with the alveolar bone. The roots are given no further attention with the exception of administering a prophylactic antibiotic immediately postsurgery and a soft diet. The roots are then observed biweekly for three months after which time reconstruction can usually be performed. The procedure is essentially similar for placement of roots in edentulous sites.

Both manual palpation and X-rays of the implants indicate when considerable ingrowth of the serrations has occurred.

Restoration

Prior to implantation of a ceramic tooth root, a gold post and core is fabricated for each root. The roots and accompanying post and core are then coded for eventual remating following implantation. This prefabrication eliminates the difficulty of taking impressions from a deeply seated implants in the oral cavity. Eventually uniform post cores can be manufactured to eliminate this intermediate step. However, the present technique is more than adequate for research purposes.

When ingrowth into the ceramic tooth root is judged to be adequate, the prefabricated post and core is cemented into position. An impression of the mouth including the post and core is then taken. A conventional gold crown is then fabricated, and cemented into place shortly thereafter. Care is taken to provide correct occlusion. The restored implant is then followed on a monthly basis. The implant is palpated for rigidity and documented by radiographs and photographs.

Histologic Preparations

Following necropsy, the area of alveolar bone including the implant is cut from the mandible of the animal and prepared for ground sectioning techniques. Initially the implant area is preserved in 70 percent ethyl alcohol. The material is then subsequently stained with basic fuchsin and imbedded in methyl methacrylate which polymerizes slowly over a period

of 1 month. The material is then sectioned using a diamond cutoff wheel. The sections are hand ground to a thickness of less than 75 microns.

Synopsis of Implant Procedure

Following is a series of figures illustrating the total implant procedure. Figure 7 shows a conical diamond burr being used to carefully shape the socket for an implant. The taper of the diamond is the same as that of the tooth root being implanted. A graded series of burrs can provide the correct buccal-lingual dimension and the burr is moved in a mesial-distal direction by the operator to accommodate the elliptical shape of the root.

A plug gage assists the operator in judging his success at creating a socket. Following correct fitting of the gage and then the root, the root is firmly tapped into position. Figure 8 shows an X-ray of a ceramic tooth root 3 months post implant. Note dense material (bone) partially filling the serrations. The immediate post-implant period of 2 to 3 months is crucial. Correct placement of the implant to minimize biomechanical stresses on the new implant is important for success. Figure 9 is a radiograph of 2 roots one 6 months post-implant on the right and a root which has been reconstructed for 12 months on the left. Note the loss of serration detail around the root which is reconstructed compared to the non-reconstructed root. This change in density is indicative of increase bone about the implant due to stress induced osteoblastic activity.

RESULTS

Within this reporting period a total of 39 tooth implants have been followed. These implants range in implant duration from 25 months to 1 month. Ten of these roots have been fully reconstructed. Of these reconstructed, only one has failed, giving overall success rate of 90 percent. The one failure occurred after four months of full function. The reason for this failure was not readily apparent. The average time



FIGURE 7. TAPERED DIAMOND BURR BEING USED TO SHAPE
SOCKET FOR ALUMINA TOOTH ROOT



FIGURE 8. NON-FUNCTIONAL TOOTH ROOT
3 MONTHS POST INSERTION

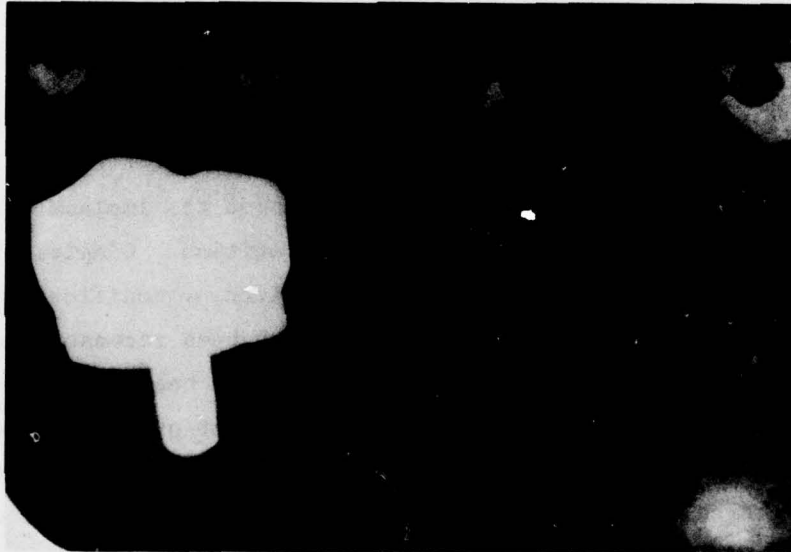


FIGURE 9. TOOTH IMPLANTS, ONE FUNCTIONAL 12 MONTHS (LEFT)
AND THE OTHER NON-FUNCTIONAL 6 MONTHS POST IMPLANT
(RIGHT)

in full function for these reconstructed roots is 12 months. It must be recalled that these roots were implanted in the animal on a average of 3 months prior to reconstruction. Consequently, the average total implant time of these roots is 15 months.

At the present time all of these roots appear successful under the following criteria:

- (1) Radiographic appearance of dense bone ingrowth into serrations.
- (2) Resistance to movement by manual palpation.
- (3) Minimal gingival irritation.
- (4) Maintenance of occlusion.

The most troublesome area of these implants appears to be gingival irritability. This is expected since there is no substitute provided for the natural gingival attachment. Bleeding about the implant can be more readily elicited than around the natural dentition. Gingival irritation appears to be diet-related, and can be minimized by modification of the diet.

Twenty-nine of the 39 roots have not been reconstructed. Of these 29 implants not in function, the total of 14 have been lost, usually within the first month after implantation. The resultant overall success rate for the first 3 months is 64 percent. This high loss rate accentuates the crucial initial ingrowth period and its importance for overall success of the implant.

Of the 14 implants lost approximately 71 percent (10) were implants placed in fresh extraction sites. This result is expected, since in fresh sites less intimate contact with the bone is obtained. Also, some roots which were not placed deep enough in alveolar bone during initial implant would eventually become mobile and were lost at varying times post-implant. High placement provides inadequate isolation from masticatory stresses during ingrowth and mobility results. These losses underscore the importance of the initial ingrowth period.

It must be recalled that these results have been obtained in an uncooperative animal species, the baboon. One would anticipate markedly better results in cooperative human subjects.

Histological Results

Figure 10 indicates the result seen at six-months post-implant at the bone ceramic interface. Note that there appears to be intimate contact between the bone formed and the ceramic tooth root. An intermediate connective tissue does not appear under light microscopy or scanning electron microscopy. This photomicrograph is from an implant which was not in full function. Figure 11 shows bone tissue interface in an implant that was in full function for 12 months. Notice the dense bone formation at the interface with the ceramic. With implants in full function, less or no connective tissue is seen intermingling with the bone as was the case in non-functional implants.

Epithelial proliferation with implants in function has not been noted below the uppermost serration. Generally it appears that successful ingrowth of bone into the serration blocks the downward migrations of epithelium. Bone appears to terminate at the depth of the first serration. Inflammatory response has not been seen with these implants.

Soft Tissue Attachment Studies

A experiment was designed to ascertain whether the band of small porosity porous material can provide a gingival attachment. Ceramic tooth roots with porous alumina filling the upper most serration were implanted into a rhesus monkey. A high failure at the time of this report (approximately 75 percent) leaves the efficacy of this technique in question. However, the failures cannot logically be attributed solely to the addition of the porous ring.

CONCLUSIONS AND RECOMMENDATIONS

The research progress indicates that the ceramic serrated tooth root can be successfully placed in full biomechanical function to provide a tooth replacement with a high probability of success. However, the high



40X

FIGURE 10. PHOTOMICROGRAPH OF TOOTH SERRATION
AT 6 MONTHS POST IMPLANT



40X

FIGURE 11. PHOTOMICROGRAPH OF TOOTH SERRATION
DETAIL IN FUNCTION FOR 12 MONTHS
BASIC FUCHSIN STAIN
(Interface separated upon grinding).

probability of success is dependant upon successful completion of an initial ingrowth period in which the serrated tooth root must be relatively free from biomechanical stresses. The most obvious improvement has been quality of the tooth roots used in this project. Use of a computer controlled milling machine for cutting the alumina roots has provided a higher quality higher strength implant with deeper serrations and consequently improved stress distribution area. Additionally, flexibility of design is now available by simple reprogramming the computer to change size or shape of ceramic root.

The most recent implant studies indicate that the ceramic tooth root designed now being employed provides excellent results. Consequently the serration detail of these roots will be retained. One minor design modification which might be desirable is the manufacture of a slightly rectangular root with rounded edges to provide better fit into fresh extraction molar sites.

It is recommended that the implants series be expanded using the baboon animal model. Further, additional experimental animals should be used for toxicology and pathology examinations which are now required for any biomedical device. These extended studies should be specifically aimed at providing adequate safety and efficacy data to assure safety and efficacy for human in vivo studies.

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